云 南 植 物 研 究 2009, Suppl. XVI: 103～109
Acta Botanica Yunnanica

Legal Issues Surrounding the Genetic Resource Conservation and Use of Edible Ectomycorrhizal Mushrooms

JONG Shung-Chang[1*], LIU Zi-Qiang[2]

(1 *Consultant for Global Affairs, ATCC,* 10801 *University Blvd*., Manassas, VA 20110-2209, USA;
2 *Edible Fungi Chamber, China Chamber of Commerce for Impart and Export of Foodstuffs, Native Produce and Animal By-Products,* 4 *F, Talent International Building, No*. 80 *Guangqumennei Street, Chongwen District,* Beijing 10062, China)

Abstract: Edible ectomycorrhizal mushrooms (EEMMs) have an enormous impact on biodiversity, global climate regulation, genetic resources as well as on global economic and social development. According to current trends in the development of intellectual property (IP) mechanisms, the use or application of EEMM genetic resources may be judged as an IP right with legal protection granted by sovereign authority. Protection of IP and proprietary rights can enhance the genetic material being used and technology being developed, prevent others from patenting the invention, recoup investments, improve trade, establish market position, preserve the identity, and generate revenues through forming strategic alliance, such as joint ventures, collaborative research agreements, joint research agreements, joint research and development agreements, manufacturing and distribution alliances, and cross-licensing arrangements. Various international agreements and treaties (such as CBD UNEP, TRIPS WTO, ITPGR FAO, GBIF OECD, Budapest Treaty WIPO) have brought together the complex issues of genetic resources and intellectual property. A number of bilateral and multilateral initiatives have been implemented to protect IP assets among the proposed users. All agreements are negotiated in a manner that is coherent with and mutually supportive of national and international laws, local customs, rules and regulations and implemented through collaborative action by governments, appropriate organizations and professional societies, field collectors and their sponsors, and curators and users of EEMM genetic materials. Lack of IP right protection will bar trade. The United States has granted favored-trading status only to those nations that meet rigid IP right protection standards.

Key words: Ectomycorrhizae; Mushrooms; Genetic resources; Conservation; Use; Legal issues
CLC number: Q 16 Document Code: A Article ID: 0253 - 2700 (2009) Suppl. XVI - 103 - 07

Introduction

Ectomycorrhizal symbiosis is an obligate association between the roots of many plant species and diverse soil fungi. It is estimated that more than 900 species of ectomycorrhizal fungi produce edible mushrooms while about 8 000 species of seed plants form ectomycorrhizas, constituting the dominant component of forest and woodland ecosystems over much of the Earth. The interdependency of this relationship is evident that a loss of ectomycorrhizal fungi would result in a loss of plant species, and hence the loss of valuable resources that might be applied to the major global issues (e.g., global warming, clean energy) facing us today. The use of advanced forest, agricultural and industrial technologies, the human population explosion, and disturbances to ecosystems by resource exploitation have resulted in reduced biological diversity and biomass. It is imperative that pertinent processes must be in place to conserve the genetic resources of edible ectomycorrhizal mushrooms (EEMMs) to ensure the forest biodiversity and to sustain its genetic parts or components in terms of ecosystems, health, equitable growth and economic viability.

The Edible Ectomycorrhizal Mushroom Genetic Resources

The benefits of the conservation and sustainable use of biological diversity are emphasized by the United Nations Convention on Biological Diversity (CBD), which requires access to and sharing of both genetic re-

Author for correspondence; E-mail: sjong@atcc.org; liuziqiang@cccfna.org.cn

sources and technologies . According to article 2 of the CBD, the term“ biological resources ”includes“ genetic resources, organisms or part of thereof, populations or any other biotic component of ecosystems with actual or potential value for humanity ”. The term“ Genetic resources ”is defined as“ genetic material of actual or potential value ”while“ genetic material ”is defined as “ any material of plant, animal, microbial or other origin containing functional units of heredity .”Being by itself not functional, DNA is the basis of heredity and thus a genetic resource as defined by the CBD .“ Biological diversity ”is a broad term that covers all levels of living organisms on the Earth, from genetic diversity within species to diversity of ecosystems, including marine and other aquatic ecosystems . Through this“ ecosystem approach ”, the CBD attempts to promote the integrated management of land, water and genetic resources to ensure conservation and sustainable use in a fair and equitable way .

The genetic resources such as the EEMMs are basic to and absolutely essential for many aspects of sustainable ecosystems, energy generation, pollution control, soil enhancement, and forest commodity production . Although matters related to the conservation and sustainable use of EEMM genetic resources and the management related to technology may appear purely technical, they have strong economic, social, political and legal implications . With technological changes, globalization and increased corporate ownership have radically changed the face of forest business which is closely integrated with other sectors of the bio-economy . This means that there are diverse professionals involved in forest value chains transforming renewable forestry material (biomass) into new sources of energy, industrial products, health-related goods and many other products and services . It is no surprise that questions posed by the emergence of intellectual property (IP) rights of EEMM genetic resources are challenging, complex, and perhaps irreconcilable .

Recognition of the intrinsic ecological, social, economic, scientific, educational, cultural and recreational values of biological diversity has contributed significantly to the genetic resource conservation and use of EEMMs . There are many different approaches to the conservation of EEMM genetic diversity, including combinations of both *ex situ* and *in situ* techniques . The CBD defines *in situ* conservation as“ the conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties .” *Ex situ* conservation is defined as“ conservation of components of biological diversity outside their natural habitats .”These approaches are complementary, but not exclusively alternative, and the requirements for any EEMM species may be met by a combination of approaches . Recent advances in biotechnology and development of molecular techniques such as molecular markers and gene sequences hold the promise of improving efficiency of managing the genetic resources . DNA banking is an emerging technique in genetic conservation, complementing gene banking .

International Treaties Impacting the Use of Genetic Resources and Edible Ectomyrrhizal Mushrooms

To incorporate human and environmental safeguards in IP and ownership rights, equitable use of EEMM genetic resources should be guided by consistent global policies under international treaties, similar to

- Convention on Biological Diversity (CBD) under the United Nations Environment Program (UNEP),
- Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS) under the World Trade Organization (WTO),
- International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGR) under the Food and Agriculture Organization (FAO),
- Budapest Treaty for the International Recognition of Deposit of Microorganisms for the Purposes of Patent Procedure under the World Intellectual Property Organization (WIPO), and
- Global Biodiversity Information Facility (GBIF) in conjunction with the Organization for Economic Cooperation and Development (OECD) .

Implementing their provisions domestically, these

international treaties allow considerable scope and flexibility for countries to take account of local, social, cultural and economic conditions and to require acceptance of the minimum standards of protection agreed to by the negotiating States. An agreement that addresses the access to and benefit-sharing of EEMM genetic resources, the transfer of environmentally sound technologies, the effect of laws and regulations, the management of risks associated with preservation and distribution of genetic materials needs to be established and enforced. To develop, implement and enforce all the agreements pertaining to such policies, IP of the EEMM genetic resources should no longer be considered as an inert legal right, but as an economic asset that realizes the potential of innovation and creativity.

The Convention on Biological Diversity

The CBD and the TRIPS agreement provide the basic framework for formation of relevant policies and laws, emphasizing the linkage between IP of genetic resources and sustainable economic development. Clearly the issue of access and benefit-sharing is a top priority for both the CBD and the TRIPS agreement. The CBD recognizes national sovereign rights over all genetic resources and establishes international rules on access, which is subject to the principles of prior informed consent and the sharing of benefits. This replaces the earlier notion, adopted by the FAO (through the Commission of Plant Genetic Resources), in which genetic resources were a common heritage of humankind and therefore were freely available to all bona fide users. However, a sovereign right is distinct from a property right over individual resources, and thus a national law is required to establish the individual property rights. The right of access is thus dependent upon the conditions established by the legislation and competent authorities of each contracting party or country. The CBD currently has 190 parties-189 States and the European Community-who have committed themselves to its three main objectives: (1) the conservation of biodiversity, (2) the sustainable use of its components, and (3) the equitable sharing of the benefits arising from utilization of genetic resources. This legally binding convention came into force on 29 December 1993.

Parties of the CBD meet at a biennial meeting (the Conference of the Parties, or COP) and agree on decisions, which then become part of the CBD. For example, the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization, adopted by the COP in 2002, provide guidance for governments developing laws and policies and for users and providers developing policies, agreements and codes of conduct. An international framework, adopted by COP in 2004, is setup to help access progress toward the "2010 Biodiversity Target" and identify focal areas, such as the status and trends of the components of biodiversity. The Bonn Guidelines further suggest elements for use in Material Transfer Agreements (MTAs) and provide a useful indicative list of benefits that may be shared. In addition, the Cartagena Biosafety Protocol, adopted by COP in 2002, promotes the safe transfer, handling and use of living modified organisms resulting from modern biotechnology. Other examples related to biodiversity, environment and trade include the Global Taxonomy Initiative (GTI), the CBD Clearing House Mechanisms on the Electronic Treatment of the Information Related Transfer of Microbiological Resources, the Global Strategy for Plant Conservation (GSPC), the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITIES), Pew Conservation Scholars' Suggested Ethical Guidelines for Accessing and Exploring Biodiversity, the FAO's Code of Conduct for Plant Germplasm Collecting and Transfer, the Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples, the Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC), and the OECD Best Practice Guidelines for Biological Resource Centers. The CBD is not retroactive but is applying only to material that is provided by countries of origin that are Parties to the Convention, and only to material that was obtained after the CBD came in force.

The Agreement on Trade-related Aspects of Intellectual Property Rights

The TRIPS agreement is the most comprehensive

international mechanism ever negotiated and adopted on IP rights . Its provisions constitute minimum standards with regard to the grant, scope and use of patent rights for biotechnological inventions . Its goals are (1) to reduce distortions and impediments to international trade, (2) to promote effective and adequate protection of IP rights, and (3) to ensure that measures and procedures to enforce IP rights do not themselves become barriers to international trade . TRIPS stresses that patents shall be available for any inventions in all fields of technology without discrimination as to the place of invention and whether products are imported or locally produced, provided that they are new, involve an inventive process and are capable of industrial application . However, the differentiation between inventions and discoveries and between the concepts of novelty and the inventive step are not defined in the TRIPS agreement . Even though equitable ownership of EEMM genetic resources is determined in the same way as ownership of patent rights, patent protection does not confer ownership of the subject matter, such as EEMM genetic material, on the patent owner . Moreover, the TRIPS agreement does not create a " uniform law ", but leaves different degrees of freedom for legislation at the national or regional level . Thus, the relationship between the TRIPS agreement and other instruments of international law, particularly the CBD and the ITPGR, has been and is still debatable, including the controversial questions whether plants, animals and DNA sequences should be made patentable and whether the disclosure of origin of biological resources should be required in the patent claim . The TRIPS agreement came into force on 1 January 1995 .

The International Treaty for Plant Genetic Resources for Food and Agriculture

The ITPGR is developed from the underlying principles of the CBD for food and agriculture . Unlike the CBD which is more oriented to bilateral arrangements, the ITPGR establishes a multilateral system for access and benefit-sharing that covers a list of crops (and crop complexes) and a number of forages of importance to food and agriculture . It is the first legally binding international treaty regarding plant genetic resource regulations concerning intellectual and other property rights and the implementation of standardized material transfer agreements (MTAs) within the multilateral system . Its aims are (1) to ensure the conservation and sustainable use of plant genetic resources as a basis for food and nutrition security, (2) to promote a fair and equitable sharing of the benefit arising from their use, and (3) to assist countries and institutions responsible for conserving these resources in identifying priorities for action and building programs to attain these purposes . As the ITPGR attempts to attain its objectives through its close links with the CBD, the conditions for the relationship between the TRIPS agreement and the ITPGR are similar to the one between the TRIPS agreement and the CBD . However, unlike many other international instruments and conventions, the ITPGR has retrospective effect, so it applies no matter when the material being transferred is acquired . The ITPGR came into force on 29 June 2004 .

The Budapest Treaty for the International Recognition of Deposit of Microorganisms for the Purposes of Patent Procedure

The most important feature of the Budapest Treaty is that a patent deposit that has been made with an independent, recognized patent depository (an International Depository Authority, or IDA approved by WIPO) satisfies the requirement of all the countries that signed the Budapest Treaty . Such a deposit is also recognized by the Paris Convention Treaty (PCT) and the European Patent Convention (EPC) as well as by the United States Patent and Trade Office (USPTO) . To date, 59 countries worldwide are party to the Treaty and 35 institutions have acquired the status of the IDA under the Treaty . The patent deposit is not a part of the patent statute . It has been created by case law and practices, in which the possibility of repeating a biotechnological invention is guaranteed by means of the deposit that is generally available (released) to third parties at the time of the disclosure . The Treaty requires that the deposited material be tested for viability . The term of the deposit is 30 years from the date

of deposit and at least 5 years after the most recent request for a sample. The Treaty does not address the timing of deposit or release. Access to the deposited material is regulated by the particular patent system under which the application was filed. Under the U. S. law, access to the deposited material can take place only after the granting of the patent. Under the European law, the material may be obtained after publication of the application through an independent expert and only for experimental purposes. As part of the patent description (e.g., European Union and Japan) or the enablement required in the patent specification (e.g., the United States) for patentibility, patent deposits can be used in providing evidence or proof of patent invalidity or infringement after the relevant patent is granted. If there is failure to supply deposited materials or no full correspondence between the description (or specification) and the deposited material, the granted patent (or claim) should be deemed void.

The Global Biodiversity Information Facility

The GBIF is an international scientific co-operative project which is based on a multilateral agreement among countries, economies and international organizations as a result of a recommendation of the OECD Megascience Forum. Its membership today includes 47 countries (26 voting participants and 21 associated participants) and 32 international organizations. Each member forms a GBIF node or nodes that are the backbone of GBIF system; and the vast majority of GBIF's scientific and technical work is done by individuals and institutions working through the nodes. Its missions are (1) to make world's biodiversity data freely and universally available via the Internet, (2) to use common standards for data and megadata, (3) to facilitate linkages among species, molecular, genetic and ecosystem data, (4) to assure that data providers retain control of their own data, and (5) to gain access to others' data by sharing theirs. To date, more than 130 million biodiversity records have been mobilized and are available for download to help Parties in the implementation of their national obligation under the CBD. The GBIF claims no IP rights on data served through its portal. Each provider decides which data to serve and sets its own policy regarding re-use of such data. Most providers do not allow the commercial use of data. In addition, the advanced instrumentation and systems which greatly speed up genome sequencing and genotypic and phenotypic analyses have brought remarkable growth in the number of genetic sequence information registered in the three major international databases, namely GenBank (National Center for Biotechnology Information, National Institutes of Health, Bethesda, Maryland, USA), EMBL (European Molecular Biology Laboratory, Nucleotide Sequence Database, Hinxton, UK) and DDBJ (DNA Data Bank of Japan, Mishima, Japan). These data are publicly available for genome analysis of various species and are updated on a daily basis. As of June 15, 2007, the registered base sequence information in GenBank NCBI has reached 73, 078, 143 entries corresponding to 77, 248, 690, 945 nucleotide base pairs.

Material Transfer Agreements

International regulatory cooperation is critical in setting standards and achieving international harmonization for trade and investment. However, how these international treaties agreements affect the access to and benefit-sharing of genetic resources is largely unresolved. Legal issues with respect to the access, transfer, exchange and patenting of EEMM genetic resources require immediate attention to ensure that resources and associated technology are fully used. One method of gaining the value of EEMM genetic resources through IP is the use of a Material Transfer Agreement (MTA) as defined by the CBD and the ITPGR. An MTA is a legal contractual arrangement that is protected by law that is neither publicly recognized nor registered with the government. It is generally utilized when proprietary material and or information, which has been characterized to some degree, but is not otherwise protected by IP rights, is exchanged for safekeeping purposes and research or commercial use. The basic aspects of an MTA generally contain (1) ownership (e.g., property rights), (2) access restrictions (e.g., no sharing with third parties), (3) use restric-

tions (e.g., research use only), (4) benefit-sharing (e.g., separate agreements required for commercialization), (5) disclosure restrictions (e.g., prepublication review), and (6) liability indemnification (e.g., biosafety, biosecurity). As shown in Appendix 1, the Bonn Guidelines provide a full list of suggested elements for use in MTAs, including some of monetary and non-monetary benefits that can be shared. However, the costs and burdens associated with the development of an effective MTA vis-à-vis the implementation of the provisions of various genetic resource-related international treaties conventions are considerably high for both the provider and the recipient. To minimize these high transaction costs that such bilateral contracts involve, the ITPGR calls for implementation of a standardized universal MTA for all ITPGR transfers through multilateral arrangements. In the United States, the NIH has published the Uniform Biological Material Transfer Agreement (UBMTA) and a Single Letter Agreement for the transfer of non-proprietary biological material. Today, there are 320 institutions signed onto the UBMTA master agreement, and for those entities, material transfers under UBMTA terms only need to be recorded but not negotiated. Although the signed contracts such as MTAs are the powerful tools in trade secret and customary laws in which registration is not required, they may be effectively meaningless without active follow-up actions, such as monitoring, tracking and or periodic reviews.

Concluding Remarks

The legal situation with respect to biodiversity and traditional knowledge, health and environmental safety, and trade and investment is very complex, and international regulations are just being developed. International access and benefit-sharing of EEMM genetic resources under the terms of various treaties conventions (such CBD UNEP, TRIPS WTO, ITPGR FAO, GBIF OECD, Budapest Treaty WIPO) must be fully recognized and respected. National frameworks on protection of IP and proprietary rights must ensure that international efforts to conserve and sustainably utilize EEMM genetic resources are duly regulated and rewarded. The EEMM genetic resources, as IP assets, are fostered and maintained not only for advancement of science and technology but also for future commercial development. It is important to underline that the objectives of CBD and TRIPS agreement do not conflict with each other from a legal perspective. International law, national legislation and contractual arrangements are complementary instruments in achieving the objectives of access to genetic resources and benefit-sharing and ensuring mutually supportive interplay between these principles and IP protection.

Concerns about access to IP assets of EEMM genetic resources have recently surfaced because of the reluctance of IP owners to allow use for research that may lead to commercial applications. In a situation where strong IP right production has been established, foreign companies can be expected to be more interested in exporting their EEMM genetic material and products derived from this material to a country with such IP protection. Lack of IP right protection will bar trade. Therefore, IP assets can be effectively be used to facilitate sustainable economic development. More laboratories, institutions, and companies are forming strategic alliances (such as collaborative research agreements, joint research and development agreements, joint ventures, and manufacturing and distribution alliances) to exploit the economic value of EEMM genetic materials, thus providing scientists and biotechnologists with the tools they need to bring their research materials and products to the marketplace.

Selected Websites:

American Type Culture Collection, Manassas, VA, USA (ATCC): http: www.atcc.org

Convention on Biological Diversity (CBD): http: www.biodiv.org

Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES): http: www cites.org

Consortium for the Barcode of Life, Smithsonian Institution's National Museum of Natural History, Washington DC, USA (CBOL): http: www.barcoding.si.edu

Consultative Group on International Agricultural Research (CGIAR): http: www.cgiar.org

DNA Data Bank of Japan, Mishima, Japan (DDBJ): http: www.ddbj.nig.ac.j

European Bioinformatics Institute, Cambridge, UK (EBI): http: www.ebi.ac.uk

European Molecular Biology Laboratory, Cambridge, UK (EMBL): http: www.embl.org

Food and Agriculture Organization of the United Nations, Rome, Italy (FAO): http: www.fao.org

Genetic Sequence Database Hosted at the NIH-NCBI, MD, USA (GenBank): http: www.ncbi.nlm.nih.gov Genbank index.html

Germplasm Resources Information Network, USDA-ARS, USA (GRIN): http: www.ars-grin.gov

Global Biodiversity Information Facility, Copenhagen, Denmark (GBIF): http: www.gbif.org

Global Strategy for Plant Conservation (GSPC): http: www.biodiv.org programmes cross-cutting plant

Global Taxonomy Initiative (GTI): http: www.biodiv.org programmes cross-cutting taxonomy

International Plant Genetic Resources Institute, Rome, Italy (IPGRI): http: www.ipgri.cgiar.org

International Society for Biological and Environmental Repositories (ISBER): http: www.isber.org

International Treaty on Plant Genetic Resources for Food and Agriculture, FAO (ITPGR): http: fao.org ag cgrfa itpgr.htm

Micro-Organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC): http: www.belspo.be bccm mosaicc

System-wide Information Network for Genetic Resources (SINGER): http: singer.grinfo.net

Trade Related Aspects of Intellectual Property Rights, WTO (TRIPS): http: www.wto.org english tratop_e trips_e.htm

World Data Center for Microorganisms (WDCM): http: www.wdcm.org

World Federation for Culture Collections (WFCC): http: www.wfcc.info

World Trade Organization, Geneva, Switzerland (WTO): http: www.wto.org

* * * * * * * * * * * * * * *

〔上接第 96 页〕

Romell L, 1906. Kan kta tryffel odlas hos oss? Tr dg rden, nr 12: 182—184

Romell L, 1907. Tryffel och tryffelodling. Tr dg rden, nr 5: 75—76

Sunhede S, 1978. *Geastrum pseudolimbatum*, *Perenniporia fraxinea* and *Tuber aestivum* found in Sweden [J]. *Svensk Botanisk Tidskrift*, 72: 263—269

Vittadini C, 1831. *Monographia tuberacearum*, Milano

Wedén C, 2004. Black truffles of Sweden. Acta Universitatis Upsaliensis. Comprehensive summaries of Uppsala dissertations from the faculty of science and technology 1043

Wedén C, Chevalier G, Danell E, 2004. *Tuber aestivum* (syn. *T. uncinatum*) biotopes and their history on Gotland, Sweden [J]. *Mycological Research*, 108: 304—310

Wedén C, Danell E, 2007. The first cultivated truffle in Scandinavia produced on Gotland [J]. *Svensk Botanisk Tidskrift*, 101: 289—291

Wedén C, Danell E, Tibell L, 2005. Species recognition in the truffle genus *Tuber*: the synonyms *T. aestivum* and *T. uncinatum* [J]. *Environmental Microbiology*, 7: 1535—1546

Wedén C, Ericsson L, Danell E, 2001. Research on *Tuber aestivum* syn. *T. uncinatum*, and *T. mesentericum* reported from Sweden for the first time [J]. *Svensk Botanisk Tidskrift*, 95: 205—211

Wedén C, Pettersson L, Danell E, 2009. Truffle cultivation in Sweden: Results from *Quercus robur* and *Corylus avellana* field trials on the island of Gotland [J]. *Scandinavian Journal of Forest Research*, 24 (1): 37—53